

**ASSEMBLY BILL**

**No. 486**

---

**Introduced by Assembly Member Bonilla**

February 23, 2015

---

An act to amend Sections 4128, 4128.4, and 4128.5 of the Business and Professions Code, relating to pharmacy, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 486, as introduced, Bonilla. Centralized hospital packaging pharmacies: medication labels.

The Pharmacy Law provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law authorizes a centralized hospital packaging pharmacy to prepare medications for administration to inpatients within its own general acute care hospital or certain other commonly owned hospitals.

Existing law requires that these medications be barcoded to be readable at the inpatient's bedside in order to retrieve certain information, including, but not limited to, the date that the medication was prepared and the components used in the drug product.

This bill would require that this information be displayed on a human-readable unit-dose label, and that the information be retrievable by the pharmacist using the medication lot number or control number.

This bill would require that the medication's barcode be machine readable, using medication administration software, and that the software compare the information contained in the barcode to the electronic medical record of the inpatient in order to verify that the medication to

be given is the correct medication, dosage, and route of administration for that patient.

Because a knowing violation of these provisions would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote:  $\frac{2}{3}$ . Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. Section 4128 of the Business and Professions  
2 Code is amended to read:

3 4128. (a) Notwithstanding Section 4029, a centralized hospital  
4 packaging pharmacy may prepare medications, by performing the  
5 following specialized functions, for administration only to  
6 inpatients within its own general acute care hospital and one or  
7 more general acute care hospitals if the hospitals are under common  
8 ownership and located within a 75-mile radius of each other:

9 (1) Preparing unit dose packages for single administration to  
10 inpatients from bulk containers, if each unit dose package is  
11 barcoded ~~pursuant to contain at least the information required by~~  
12 Section 4128.4.

13 (2) Preparing *sterile* compounded unit dose drugs for ~~parenteral~~  
14 ~~therapy for~~ administration to inpatients, if each compounded unit  
15 dose drug is barcoded ~~pursuant to contain at least the information~~  
16 ~~required by~~ Section 4128.4.

17 (3) Preparing compounded unit dose drugs for administration  
18 to inpatients, if each unit dose package is barcoded *pursuant to*  
19 ~~contain at least the information required by~~ Section 4128.4.

20 (b) For purposes of this article, “common ownership” means  
21 that the ownership information on file with the board pursuant to  
22 Section 4201 for the licensed pharmacy is consistent with the  
23 ownership information on file with the board for the other licensed

1 pharmacy or pharmacies for purposes of preparing medications  
2 pursuant to this section.

3 SEC. 2. Section 4128.4 of the Business and Professions Code  
4 is amended to read:

5 4128.4. (a) Any unit dose medication produced by a  
6 centralized hospital packaging pharmacy shall be barcoded to be  
7 machine readable at the inpatient's bedside. Upon reading the  
8 barcode, the following information shall be retrievable: bedside  
9 using barcode medication administration software.

10 ~~(a) The date the medication was prepared.~~

11 (b) The components used barcode medication administration  
12 software shall permit health care practitioners to ensure that,  
13 before a medication is administered to an inpatient, it is the right  
14 medication, for the right inpatient, in the drug product, right dose,  
15 and via the right route of administration. The software shall verify  
16 that the medication satisfies these criteria by reading the barcode  
17 on the medication and comparing the information retrieved to the  
18 electronic medical record of the inpatient.

19 ~~(c) The lot number or control number. For purposes of this~~  
20 ~~section, "barcode medication administration software" means a~~  
21 ~~computerized system designed to prevent medication errors in~~  
22 ~~health care settings.~~

23 ~~(d) The expiration date.~~

24 ~~(e) The National Drug Code Directory number.~~

25 ~~(f) The name of the centralized hospital packaging pharmacy.~~

26 SEC. 3. Section 4128.5 of the Business and Professions Code  
27 is amended to read:

28 4128.5. ~~The~~ (a) Any label for each unit dose medication  
29 produced by a centralized hospital packaging pharmacy shall  
30 ~~contain~~ display a human-readable label that contains all of the  
31 following:

32 (a)

33 ~~(1) The expiration date, date that the medication was prepared.~~

34 ~~(2) The beyond-use date.~~

35 (b)

36 (3) The established name of the drug.

37 (c)

38 (4) The quantity of the each active ingredient.

39 ~~(d)~~

40 (5) Special storage or handling requirements.

1     (6) *The lot number or control number assigned by the*  
2     *centralized hospital packaging pharmacy.*

3     (7) *The name of the centralized hospital packaging pharmacy.*

4     (b) *For quality control and investigative purposes, a pharmacist*  
5     *shall be able to retrieve all of the following information using the*  
6     *lot number or control number described in subdivision (a):*

7         (1) *The components used in the drug product.*

8         (2) *The expiration date of each of the drug's components.*

9         (3) *The National Drug Code Directory number.*

10     SEC. 4. No reimbursement is required by this act pursuant to  
11     Section 6 of Article XIII B of the California Constitution because  
12     the only costs that may be incurred by a local agency or school  
13     district will be incurred because this act creates a new crime or  
14     infraction, eliminates a crime or infraction, or changes the penalty  
15     for a crime or infraction, within the meaning of Section 17556 of  
16     the Government Code, or changes the definition of a crime within  
17     the meaning of Section 6 of Article XIII B of the California  
18     Constitution.

19     SEC. 5. This act is an urgency statute necessary for the  
20     immediate preservation of the public peace, health, or safety within  
21     the meaning of Article IV of the Constitution and shall go into  
22     immediate effect. The facts constituting the necessity are:

23     To eliminate, at the earliest possible time, requirements that  
24     exceed the current technological capabilities of hospitals and that  
25     create overly burdensome administrative costs for the California  
26     State Board of Pharmacy, it is necessary this act take effect  
27     immediately.